The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

Paper No. 20

#### UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte PHILIP S. PORTOGHESE

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Application No. 08/440,989

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ON BRIEF

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Before WINTERS and WILLIAM F. SMITH, <u>Administrative Patent Judges</u>, and McKELVEY, <u>Senior Administrative Patent Judge</u>.

WINTERS, Administrative Patent Judge.

#### **DECISION ON APPEAL**

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 21, the only claim pending in the application.

Claim 21 reads as follows:

21. A method for blocking  $\delta$ -opioid receptors in mammalian tissue comprising contacting said receptors with an amount of a compound of the formula:

$$R^{3}$$
 0  $R^{4}$ 

wherein  $R^1$  is  $(C_1-C_5)$ alkyl,  $C_3-C_6$ (cycloalkyl)alkyl,  $C_5-C_7$ (cycloalkenyl)alkyl,  $(C_6-C_{10})$ aryl,  $(C_6-C_{10})$ aryl $(C_1-C_5)$ alkyl, trans $(C_4-C_5)$ alkenyl, allyl or furan-2-ylalkyl;  $R^2$  is H, OH or  $O_2C(C_1-C_5)$ alkyl;  $R^3$  is H,  $(C_1-C_5)$  alkyl, or  $((C_1-C_5)$ alkyl)C=O; and  $R^4$  and  $R^5$  are individually H, F, Cl, Br, NH<sub>2</sub>, NO<sub>2</sub>,  $(C_1-C_5)$  alkyl or  $(C_1-C_5)$  alkoxy or  $R^4$  and  $R^5$  together are benzo or dioxymethylene; and the pharmaceutically acceptable salts thereof, wherein the amount is effective to block  $\delta$ -opioid receptors in said tissue.

#### THE REFERENCES

In rejecting claim 21 on prior art grounds, the examiner relies on this reference:

Portoghese et al., "Role of the spacer in conferring κ opioid receptor selectivity to bivalent ligands related to norbinaltorphimine," <u>J. Med. Chem.</u>, Vol. 34, No. 4, pp. 1292-1296 (1991)

In rejecting claim 21 on non-prior art grounds, the examiner relies on this reference:

Stillson et al. (Stillson), "The hindered phenols," <u>Journal American Chemical Soc.</u>, Vol. 67, pp. 303-307 (1945)

# Grounds of Rejection

Claim 21 stands rejected under (1) 35 U.S.C. § 102(a) as anticipated by Portoghese et al.; and (2) 35 U.S.C. § 112, first and second paragraphs, as based on a non-enabling disclosure "and/or" failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On consideration of the record, we reverse these rejections.

# Background

The claimed invention is directed to a method for blocking  $\delta$ -opioid receptors in mammalian tissue comprising contacting said receptors with an effective amount of a compound of the formula:

$$R^{3} \cdot 0$$
 $R^{2}$ 
 $R^{5}$ 
 $R^{5}$ 

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where  $R^1$  is  $(C_1-C_5)$  alkyl,  $C_3-C_6$  (cycloalkyl)alkyl,  $C_5-C_7$  (cycloalkenyl)alkyl,  $(C_6-C_{10})$  aryl,  $(C_6-C_{10})$  aryl,  $(C_1-C_5)$  alkyl, trans( $C_4-C_5$ ) alkenyl, allyl or furan-2-ylalkyl;  $R^2$  is H, OH or  $O_2C(C_1-C_5)$  alkyl;  $R^3$  is H,  $(C_1-C_5)$  alkyl, or  $((C_1-C_5)$  alkyl)C=O; and  $R^4$  and  $R^5$  are individually H, F, Cl, Br,  $NH_2$ ,  $NO_2$ ,  $(C_1-C_5)$  alkyl or  $(C_1-C_5)$  alkoxy or  $R^4$  and  $R^5$  together are benzo or dioxymethylene (specification, page 4). According to appellant, "[i]t is believed that compounds of [this] formula ... can decrease ethanol consumption by mammals without decreasing the intake of food or water for prolonged periods of time" (specification, page 5).

## **DISCUSSION**

I. Rejection under 35 U.S.C. § 102(a)

Claim 21 stands rejected under 35 U.S.C. § 102(a) as anticipated by Portoghese et al. Specifically, the examiner refers to 7-benzylidene-7-dehydronaltrexone, which is illustrated in Scheme II of the reference at page 1293 (compound 7) and described further in the experimental section at page 1296, column 2, last paragraph. The examiner also refers to the disclosed biological activity of compound 7 in Portoghese et al., page 1295, column 2, second complete paragraph (Examiner's Answer, page 10). Appellant does not dispute that 7-benzylidene-7-dehydronaltrexone is a species within the genus of compounds recited in claim 21; or that claim 21 "reads on" a method described by Portoghese et al.; or that Portoghese et al. constitutes an anticipatory reference if it constitutes legally available prior art. The only dispute is whether Portoghese et al.

constitutes legally available prior art under 35 U.S.C. § 102(a) where co-authors Garzon-Aburbeh, Nagase, Lin and Takemori are not listed as coinventors in this application. We will not sustain this rejection.

As prescribed in 35 U.S.C. § 102(a), a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. One's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar. In re Facius, 408 F.2d 1396, 1406, 161 USPQ 294, 302 (CCPA 1969). Further, as stated in In re Katz, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982), "authorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article." Thus "co-authors may not be presumed to be coinventors merely from the fact of co-authorship." Id.

In <u>Katz</u>, the court accepted a declaration by appellant explaining that two co-authors of the Chiorazzi et al. publication "were students working under the direction and supervision of the inventor, Dr. David H. Katz." <u>Id</u>. According to the court, this declaration provided "a clear alternative conclusion to the board's inference that their names were on the article because they were coinventors." <u>Id</u>.

In the instant case, appellant has averred in the declaration accompanying this application that he is the original, first, and sole inventor of the subject matter which is

claimed (Combined Declaration and Power of Attorney, page 1). Appellant re-averred his status as the sole inventor of compound 7, illustrated in Scheme II of Portoghese et al., in a Declaration under 37 CFR § 1.132 filed as Paper No. 21 on November 10, 1993 in parent Application No. 07/867,997 (also filed as Paper No. 11 on February 20, 1996 in this application). In the same declaration, appellant described the type of contribution made by Garzon-Aburbeh, Nagase, Lin and Takemori, resulting in their acknowledgment as coauthors of the Portoghese et al. publication, but consistent with appellant's sworn statement that he is the sole inventor of compound 7 (Paper No. 11, paragraphs 5, 6, and 7).

On these facts, we find that <u>In re Katz</u> is controlling; that the declaration evidence provides "a clear alternative conclusion" to the examiner's inference that the name of coauthor Takemori appears on the Portoghese et al. publication because he (Takemori) is a coinventor; and that there is no reason to look behind appellant's declaration (Paper No. 11).

Accordingly, we hold that the Portoghese et al. reference does not constitute legally available prior art, and we <u>reverse</u> the examiner's rejection under 35 U.S.C. § 102(a).

II. Rejection under 35 U.S.C. § 112, first and second paragraphs

Claims 21 also stands rejected under 35 U.S.C. § 112, first and second paragraphs, as based on a non-enabling disclosure "and/or" failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (Examiner's Answer, page 4).

Respecting the issue of indefiniteness under 35 U.S.C. § 112, second paragraph, we observe that "the definiteness of the language employed [in a claim] must be analyzed-not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

In arguing that claim 21 does not comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph, the examiner sets forth a series of cryptic, staccato-like questions (Examiner's Answer, page 5). The examiner does not, however, provide any analysis of what the specification discloses or how persons skilled in the art would read claim 21 in light of the specification. Absent such analysis, we will not sustain this rejection.

Invoking the rubric of "undue experimentation" under 35 U.S.C. § 112, first paragraph, the examiner questions appellant's disclosure respecting "how to use" mammalian tissue with blocked opiate receptors (Examiner's Answer, page 4), the breadth of "mammalian tissue" (Examiner's Answer, page 5), and "how to make" certain embodiments encompassed by the claims (Examiner's Answer, page 8). By now it is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). It has long been held that "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed

invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Further guidance on this issue is provided in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988), stating that:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in <a href="Ex parte">Ex parte</a>
Forman, [230 USPQ 546, 547 (Bd. Pat. App. Int. 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted).

The <u>Wands</u> factors are illustrative, not mandatory. All of the factors need not be reviewed when determining whether a disclosure is enabling. <u>Enzo Biochem Inc. v. Calgene Inc.</u>, 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). They provide the decision-maker with guidance in resolving the question of enablement under 35 U.S.C. § 112, first paragraph.

On consideration of the record, we will not sustain this rejection for the reasons succinctly set forth on pages 10 through 14 of the appeal brief. In our judgment, the examiner has not provided adequate reasons to doubt the objective truth of statements made in appellant's specification. The examiner's arguments are insufficient to establish

that the specification does not enable any person skilled in the art to make and use the claimed invention, taking into account the relevant factors set forth in <u>Wands</u>.

The rejection under 35 U.S.C. § 112, first and second paragraphs, is reversed.

### CONCLUSION

The examiner's decision, rejecting claim 21 under 35 U.S.C. § 102(a), and 35 U.S.C. § 112, first and second paragraphs, is <u>reversed</u>.

#### **REVERSED**

SHERMAN D. WINTERS Administrative Patent Judge	) ) )
WILLIAM F. SMITH Administrative Patent Judge	) ) BOARD OF PATENT ) ) APPEALS AND
	) INTERFERENCES
FRED E. MCKELVEY Senior Administrative Patent Judge	) ) )

Appeal No. 1997-2204 Application No. 08/440,989

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